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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,861	12/05/2003	Yunhai Cui	1710.002US1	8500

7590 08/28/2006

Schwegman, Lundberg, Woessner & Kluth, P.A.
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EXAMINER

BURKHART, MICHAEL D

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,861

Applicant(s)

CUI ET AL.

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/5/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt and entry of the amendment dated 4/5/2006 is acknowledged. After entry of the amendment, claims 1-8 and 10-13 are pending and under examination.

Drawings

Applicants petition to accept color drawings is granted.

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER



Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 13 recite the limitation "the opposite compartment" in lines 6 and 9, respectively. There is insufficient antecedent basis for this limitation in the claims. **This is a new rejection necessitated by amendment of the claims.**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **These are new rejections necessitated by amendment of the claims.**

Amended claim 1 (from which all other claims depend) recites a cell line transfected with DNA encoding "an uptake transporter for organic anions from the solute carrier (SLC) superfamily" and "an export pump from the ATP-binding cassette (ABC) superfamily." The response does not indicate where support for the amendment may be found in the specification. A search of the specification reveals that support for the claimed cell line exists using transporters of subgroups 21A and 22A of the SLC superfamily (e.g. ¶ [0013] of the published application) and export pumps of the MDR and MRP subgroups of the ABC superfamily (e.g. ¶ [0014] of the published application). There is no indication that applicants contemplated all members or subgroups of the SLC or ABC superfamilies as a part of their invention. Therefore, there is no support for the limitations "an uptake transporter for organic anions from the solute carrier (SLC) superfamily" or "an export pump from the ATP-binding cassette (ABC) superfamily." Thus, the amended claims include impermissible New Matter.

Amended claim 12 recites a method of identifying whether a candidate agent is a transport inhibitor by contacting the cells of claim 1 with the candidate agent and determining the subsequent location of the agent. In order to identify a transport inhibitor, the instant method must measure the transport of some molecule (e.g. a transport substrate) mediated by the cells of claim 1, then determine whether this transport activity is modulated by the candidate agent. The claim does not recite a transport substrate, thus the candidate agent in the claim is both the potential transport inhibitor and transport substrate. The response does not indicate where support for the amendment may be found in the specification. A reading of the specification

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reveals methods wherein inhibition of the transport of 3H-labeled substrates (e.g. rifampicin, BSP) was studied using the claimed cell lines and inhibitors (e.g. CDNB). See ¶'s [0039]-[0042] of the published application. There is no disclosure of the claimed method wherein no transport substrate is used and the candidate agent is both inhibitor and transport substrate, as instantly recited in claim 12. Thus, the amended claims include impermissible New Matter.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

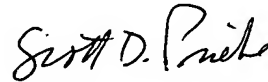
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
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A handwritten signature in black ink, appearing to read "Scott D. Pribe". The signature is written in a cursive, flowing style.

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER